REMARKS

Amendments

Independent claim 1 has been amended to recite the restrictive member being a single sheet membrane and the restrictive member being substantially planar with a plane of the anchor. Independent claim 1 has further been amended to recite an anchor configured to be fixedly coupled to the stomach and removably coupled to the restrictive member with a mechanical feature.

Independent claim 49 has been amended to reflect the previous and current amendments to claim 1. The Examiner has stated in the "Response to Arguments" that claim 49 was not amended to recite the planar dimension of 7-20cm. Claim 49 has now been amended to recite this limitation, as well as additional limitations of claim 1, and should thus now be allowable over Kagan as were the other claims.

Further, claims 1-20 have been rejected under 35 U.S.C. 112 as being indefinite for minor informalities. These informalities have been corrected with the amendments to claim 1. This rejection should therefore be overcome.

Also, claims 14-16 have been rejected under 35 U.S.C. 112 as being indefinite. These claims have been cancelled to overcome the rejection.

Claim 19 has been cancelled as its limitation has been added to independent claim 1. New claim 50 has been added.

102 Rejections

Claim 49 has been rejected under 35 U.S.C. 102(e) as being anticipated by Kagan et al (US 2005/0240279).

As the Examiner has stated in the "Response to Arguments," claim 49 was not amended to recite the planar dimension of 7-20cm. Claim 49 has now been amended to recite this limitation, as well as additional limitations of claim 1, and should thus now be allowable over Kagan as were the other claims.

Disclosed embodiments will be discussed without limitation of the claims. As shown in Applicant's Figure 2, a restrictive device is implanted by a physician in the upper part of the

stomach. The restrictive device can be a two-piece device including an anchoring cuff 217 and a removable restrictive member 224 with an aperture 218 through which food transits. The removable member can have an exterior perimeter sized to contact inner walls of the stomach. For example, the restrictive member can have an external diameter between about 7 and about 20 centimeters. The anchoring cuff is fixedly coupled to the stomach, and the restrictive membrane is removably coupled to the anchoring cuff. The restrictive member can be planar in shape and is substantially planar with the anchor. The restrictive member is a single-sheet membrane.

First, the restrictive device divides the stomach into two chambers: an upper chamber, near the esophagus, and a lower chamber. Dividing the interior of the stomach in this manner restricts the volume of the upper stomach available to hold ingested food. Thus, the size of the stomach immediately available for food is effectively reduced in a minimally invasive manner. Preferably, the upper stomach chamber has a volume between about 30 and about 100 cubic centimeters (cc).

The positioning of the device in the upper stomach is advantageous in many ways. Firstly, the location in the upper stomach is safer as compared to devices positioned in the esophagus or gastro esophageal junction (GEJ). Interfering with GEJ valve function, as does an esophageal device, can cause serious safety concerns. Being anchored in the upper stomach as opposed to in the GEJ prevents interference with normal gastro esophageal functions.

Further, the width of the restrictive member (between about 7-20 cm to match the stomach size and depending on the size of the stomach pouch desired) allows it to sit in the stomach while placing minimal tension on the stomach.

Additionally, the removable restrictive member permits the physician to change the size of the opening of the restrictive member in a minimally invasive manner by replacing the member with another member having an aperture of a different size and/or shape.

Also, the planar shape of the membrane is advantageous in that one can obtain a small volume above the member with the device mounted to the stomach just below the GEJ.

For example, an esophageal valve type device or any hanging valve/pouch device would not function adequately in the stomach as does Applicant's device. In order to create an upper stomach chamber between 30-100 cc as is preferred by the Applicant, a device that itself had a

significant length and resultant volume would need to be anchored high within the GEJ. Thus, Applicant's planar shape and its being planar with a plane of the anchor allows it to be placed anywhere within the stomach to fully control the size of the desired chamber, even to a small volume. A pouch or valve on the other hand, also has additional volume to consider when creating the stomach chamber.

Kagan describes an apparatus for treatment of morbid obesity. Kagan's device can be seen in Kagan's Figure 1. The first component is an artificial stoma 100 located in the stomach or lower esophagus that reduces the flow of food into the stomach. The stoma can be anchored to the esophageal or stomach wall using sutures, staples, clips, or other anchoring mechanisms. It can also be used in conjunction with gastric suturing, stapling, or banding to create a narrow passage for installation of the stoma and for reduction of gastric volume, as seen in Figure 1. The artificial stoma can include a fabric cuff on the outer circumference to facilitate in-growth of tissue to secure the device. Alternatively, the stoma device can include a separate anchoring device that is in the form of an anchoring ring like the one shown in Figures 2A-2B.

Kagan does not describe substantially planar restrictive member as does the Applicant. Kagan also does not describe a restrictive member that is substantially planar with the anchor, or the restrictive member being a single-sheet membrane as does the Applicant. The shape of Kagan's stoma can be seen in Figures 7A-7B.

Further, Kagan does not describe the restrictive member having an outer width between 7 and 20 centimeters. In the embodiments where Kagan's stoma and anchoring ring contact the walls of the stomach, the walls of the stomach are pulled to create a narrowing. The stoma itself is not sized to sit in the stomach as is Applicant's planar restrictive member and anchor. As stated, the width of Applicant's planar restrictive member between about 7-20 cm matches the stomach size and allows it to sit in the stomach while placing minimal tension on the stomach.

Therefore, Kagan does not teach all of the limitations of amended claim 49, and thus claim 49 is allowable over Kagan.

103 Rejections

Claims 1-10, 12, 13, and 17-19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (US 5,925,063). Claims 11 and 20 have been rejected as being

unpatentable over Khosravi in view of Saadat (US 7,160,312). Finally, claims 1-14 and 17-20 have been rejected as being unpatentable over Stack et. al (US 7,146,984).

Khosravi describes a coiled sheet having a plurality of flaps mounted on its interior surface that project radially inward into a lumen formed by the interior surface of the apparatus when it is deployed (Khosravi, Abstract). The flaps can act as a filter, valve, or occlusive device (Khosravi, Col. 5, lines 56-64).

Firstly, Khosravi does not describe a restrictive member that is a single sheet membrane as does the Applicant. Khosravi's device is made up of a plurality of flaps, not a single planar sheet. Further, Khosravi does not specifically describe the restrictive member being 7-20cm such that it fits the upper stomach as does the Applicant.

Additionally, Khosravi does not describe an anchor that is removably coupled to the restrictive member with a mechanical feature as does the Applicant. Looking at Khosravi's FIG. 2, Khosravi discloses that the flaps are affixed to the sheet 21 along a marginal portion 29 using any suitable means, including welding, brazing, or the use of a biocompatible adhesive (Khosravi, Col. 4, lines 36-40).

None of these mechanisms are considered a "mechanical feature" for removably coupling the member to the anchor. Welding and brazing are generally not intended to be removable mechanisms of coupling. Additionally, none of these mechanisms are additional mechanical features, as for example is Applicant's loop (see claim 12).

Thus, Khosravi does not describe all of the limitations of independent claim 1. Specifically, Khosravi does not describe the restrictive member being a single sheet membrane, an anchor removably coupled to the restrictive member with a mechanical feature, or the member being 7-20 cm in diameter. Therefore, independent claim 1 or any claim dependent on the same is allowable for at least these reasons.

Though the dependent claims are allowable over Khosravi, dependent claim 13 is further addressed herein. Referring to Khosravi's Figures 2 and 6C, the Examiner states that Khosravi discloses an anchor having a plurality of clips 24. Khosravi refers to teeth 24 that are engaged with openings 26 in edge 27. These are not spring clips configured to penetrate the muscular tissue of the stomach as is recited in Applicant's claim 13 and new independent claim 50. These

are simply teeth that lock the device itself. Therefore, dependent claim 13 and new claim 50 are allowable over Khosravi for this reason.

Further, dependent claims 11 and 20 have also been rejected over Khosravi in light of Saadat. Saadat describes a plurality of anchors adapted for intraluminal penetration into a wall of a gastro-intestinal lumen to prevent migration or dislodgement of the apparatus (Saadat, Abstract.)

Khosravi does not describe all of the limitations of independent claim 1, as previously stated. Saadat also does not describe any of the limitations of independent claim 1. Thus, neither reference either alone or in combination describe all of the limitations of independent claim 1, making this claim or any claim dependent on claim 1 allowable for at least this reason.

Claims 1-14 and 17-20 have also been rejected over Stack et. al.

As shown in Stack's embodiment in Figures 5A and 5B, Stack describes a pouch 40 to be implanted in the gastroesophageal region. The pouch 40 has an annular web 42 at its distal end, forming a distal orifice 44. A ring 46 is connected to the exterior of the webbing.

The examiner states that Stack discloses the implant for placement in the stomach substantially as claimed, however does not disclose the size (width) of the restrictive member and of the aperture. The Examiner further states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) since such modification would have involved a mere change in size of the component, and since Stack's implant is being placed in the same location as the Applicant's device.

Applicant respectfully disagrees. Firstly, Stack's device is not placed in the stomach but in the gastroesophageal region. Thus, it is not obvious to make it of a size to fit the perimeter of the stomach.

Further, Stack does not describe a restrictive member that is planar with a plane of the anchor as is described by the Applicant. Stack's annular web is not planar with the anchor but is at the distal end of the pouch. In summary, Stack's device is a hanging gastroesophageal pouch with an orifice at the distal end.

As previously stated, a device like Stack's would not function adequately in the stomach as does Applicant's device. In order to create an upper stomach chamber between 30-100 cc as is preferred by the Applicant, a device that itself had a significant length and resultant volume

would need to be anchored high within the GEJ. Thus, Applicant's member being planar with the anchor allows it to be placed anywhere within the stomach to fully control the size of the desired chamber, even to a small volume. Stack's pouch also has additional volume to consider when creating the stomach chamber.

Thus, Stack does not describe all of the limitations of amended claim 1. Specifically, Stack does not describe the restrictive member having an outer width between 7 and 20 centimeters, and the restrictive member being substantially planar with a plane of the anchor. Therefore, claim 1 or any claim dependent on claim 1 is allowable over Stack for at least these reasons.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By _____

Sumedha A. Bahri
Registration No. 57,427
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Date: 12/11/07